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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,673	08/19/2003	Suong-Hyu Hyon	1736-000001/REC	5763
27572	7590	05/18/2005		EXAMINER
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/643,673	HYON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Susan W Berman	1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-148 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12-148 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

***Reissue Applications***

This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172(a)*. The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b). Applicant's statement has the party who is signing also stating that he is "empowered to sign this certificate". The language the party is "empowered to sign this certificate" instead of "the party is empowered to act on behalf of the assignee" is acceptable; however, the same person who is making the statement also signing the consent form is not acceptable.

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

A copy of the new claims 12-148 submitted 08/19/2003 should be included with the response to this Office Action because new claims submitted in a reissue application must be underlined in their entirety. See 37 CFR 1.173(d).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-148 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

Art Unit: 1711

at the time the application was filed, had possession of the claimed invention. The specification does not describe the following subject matter employed in the claims:

1. "polyethylene", "preformed polyethylene" or "orthopedic preformed material", "medical implant" or "prosthesis", "bearing surface" or "load bearing component": The recitation of "polyethylene", "preformed polyethylene" or "orthopedic preformed material", instead of "ultra-high molecular weight polyethylene (UHMWPE)" or "ultra-high molecular weight polyethylene (UHMWPE) article" broadens the scope of subject matter described in the specification as originally filed. The recitation of "medical implant" or "prosthesis" instead of "molded article for artificial joints", "artificial joints" or "socket for artificial joints" broadens the scope of subject matter originally described in the specification since medical implants other than artificial joints are known in the art. The recitation of "bearing surface" or "load bearing component" instead of "acetabular cup", "hip joints" or "knee joints" broadens the scope of the subject matter originally described in the specification because other kinds of bearing surfaces or load bearing components are encompassed by the claim language.

2. "annealing", "subsequently annealing", "remelting" or "subsequently remelting": The recitation of "annealing", "subsequently annealing", "remelting" or "subsequently remelting" is not commensurate in scope with the disclosure as originally filed. The specification describes a process of "compression deformation" at a compression deformable temperature and a process of "isothermal crystallization" of the compression deformed material.

3. a temperature between "about" 50<sup>0</sup>C below the melting temperature and the melting temperature, a temperature from the melting temperature of the irradiated polyethylene to "about" 80<sup>0</sup>C above the melting temperature: The recitation of heating to a temperature "between about" 50<sup>0</sup>C below the melting temperature of said irradiated polyethylene and the melting temperature of said irradiated polyethylene is not considered to be supported by the description of compression-deformation of irradiated UHMWPE at a temperature from the melting point minus 50<sup>0</sup>C (see claims 28, 43, 51, 63, 80,

Art Unit: 1711

91, 99, 104, 105, 114, 115, 122, 135, 144). The recitation of remelting at a temperature from the melting temperature of the irradiated polyethylene to “about” 80<sup>0</sup>C above the melting temperature of the irradiated polyethylene is not considered to be supported by the original description of compression-deformation of irradiated UHMWPE at a temperature from the melting point to the melting point plus 80<sup>0</sup>C (see claims 21, 50, 53, 71, 104, 107, 114, 117, 122, 125, 136, 145).

4. isothermal treatment at a temperature of from about 100<sup>0</sup>C to about 130<sup>0</sup>C for “about” 1 hour to “about” 20 hours: The recitation of subsequent isothermal treatment at a temperature of from about 100<sup>0</sup>C to about 130<sup>0</sup>C for “about” 1 hour to “about” 20 hours is not considered to be supported by the disclosure of isothermal treatment for 1 to 20 hours (see claims 29, 44, 64, 81, 92, 100, 106, 111, 116, 124, 130, 131, 139, 140).

5. heating the article isothermally after pressure is applied: The recitation of heating a raw article comprising UHMWPE isothermally after pressure is applied is not found within the specification , which discloses subjecting a compression-deformed UHMWPE molded article to isothermal crystallization (see claim 110).

6. an irradiation dose of “at least” 1 MR or of “about” 5 MR: The recitation of an irradiation dose of “at least about” 1 MR or about 1 MR or “about” 5 MR is not supported by the disclosure of an irradiation dose of 1.0 MR to 5.0 MR (see claims 19, 20, 31, 32, 40, 41, 48, 49, 56, 57, 60, 61, 68, 69, 73, 74, 77, 78, 87, 88, 95, 96).

7. irradiation in a “solid state”: The recitation of irradiating polyethylene in a “solid state” is not considered to be supported by the description of irradiation of an UHMWPE “molded article”, “block” or “rod” (see claims 38, 46).

8. removing a layer or surface of the crosslinked, remelted or annealed polyethylene during processing: The examiner has not found a description of removing a layer or surface of the crosslinked,

Art Unit: 1711

remelted or annealed polyethylene during processing within the specification as filed (see claims 22, 33, 46, 66, 85, 93).

9. "fashioning" the implantable bearing component: The recitation of "fashioning" the implantable bearing component is not considered to be supported by the description of "processing" the compression-deformed molded article by "cutting" or molding to obtain an article for artificial joints (see claims 75, 85, 93).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 113, 121, 129, 138 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is encompassed by a wear factor of "less than about"  $9.6 \times 10^{-7}$ . If applicant intends to claim a wear factor of "less than"  $9.6 \times 10^{-7}$ , it should be so stated. If applicant intends to claim a wear factor of "about"  $9.6 \times 10^{-7}$ , it should be so stated.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 15, 16, 27, 28, 30-43, 45-63, 65-69, 75-78, 80-88, 90-96, 98-104, 108-110, 112-114, 118-122, 126-130, 134-139 and 143-148 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al (5,414,049). Sun et al disclose a process for providing an implant from UHMWPE. Sun et al

teach that irradiation in the absence of air produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin into an UHMWPE raw material, irradiating a packaged implant of the UHMWPE raw material at a sterilizing dose of about 2.5 Mrad, and heat treating at temperatures below the melting point after irradiation to form crosslinks between free radicals produced upon irradiation. Sun et al teach shaping the treated UHMWPE by cutting in the Examples. See column 4, lines 20-43, column 6, line 42, to column 7, line 8, methods B, C and D and the Examples.

Instant claims 12, 13, 15, 16, 38-43, 45, 58-63 and 65 are considered to be anticipated wherein annealing is selected as the method for thermal treatment. Sun et al disclose 2.5 Mrad, which is within the range 1 to 5 MR set forth in the instant claims. Sun et al teach heating the irradiated UHMWPE molded article at temperatures from 25 °C to 140 °C, thus disclosing temperatures within the temperature range set forth in the instant claims.

Instant claims 27, 28, 30-32, 34-37, 104, 108-110, 112-114, 118-122, 126-130, 134-139 and 143-148 are considered to be anticipated because the claims do not specify the order of irradiating and heating steps or distinguish between compression deformation heating (claims 104, 105, 107, 108, 109, for example) and isothermal crystallization heating (claims 106, 110, 111, for example). Thus step (b) in the claims, as written, can comprise compression-deforming heating carried out before irradiating the raw article, as disclosed by the equivalent melting and forming step taught by Sun et al. Alternatively, heating step (b) in the claims, as written, can comprise isothermal crystallization carried out after irradiation, as disclosed by the equivalent heat treatment of the irradiated implant taught by Sun et al. With respect to claims 105, 107, 115, 117, 123, and 125, Sun et al specifically discloses melting and forming at the melting temperature. With respect to claims setting forth the wear factor of "less than about"  $9.6 \times 10^{-7}$ , this property is considered to be an inherent property of the molded articles disclosed by Sun et al, in the

absence of evidence to the contrary, because the method steps taught by Sun et al correspond to those set forth in the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 29, 43, 44, 63, 64, 105-107, 111, 114-117, 122-125, 130-133, 135, 136, 139-142, 144, and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. See the discussion of Sun et al above. Sun et al disclose melting and forming a polymeric resin into a raw material for forming an implant, corresponding to the instantly disclosed compression –deformation step, but do not mention the temperature ranges for compression deformation set forth in instant claims 105, 107, 115, 117, 123, 125. Sun et al disclose heat treatment corresponding to isothermal recrystallization wherein the temperature range is between about 25 °C and about 140 °C, preferably from 37° C to about 70° C or the heating is for at least 48 hours at a temperature from 37° C to about 70° C and preferably for 144 hours at 50° C. Sun et al also teach that the higher the temperature the shorter the time period required for crosslinking (column 6, lines 58-61).

It would have been obvious to one skilled in the art at the time of the invention to determine the optimum temperature for forming and melting a selected UHMWPE polymeric resin into a raw material for forming an implant because the melting temperature of UHMWPE materials is related to the molecular weight of the material and is published and well known and/or can be readily determined experimentally. It would have been obvious to one skilled in the art at the time of the invention to determine the optimum temperature and time for isothermal recrystallization required to form crosslinks

Art Unit: 1711

between the free radicals present in an irradiated UHMWPE material from the teaching of Sun et al with respect to times and temperatures. It would have been obvious to one skilled in the art at the time of the invention to employ a higher temperature and shorter time if the packaging material could withstand the higher temperature or if the material were treated in an inert gas environment rather than being packaged in a packaging material to exclude oxygen. With respect to claims 132-133 and 141-142, it would have been obvious to one skilled in the art to determine the rate of cooling required to obtain the desired properties since the effects of cooling rate are well known in the art with respect to polyethylene materials. See the numerous articles and trade literature cited by applicant. One of ordinary skill in the art at the time of the invention would have been motivated to determine the optimum temperature for forming and melting a specific UHMWPE resin and/or determine the optimum time and temperature for recrystallization and/or determine the optimum cooling rate using the process steps taught by Sun et al by a reasonable expectation of providing a polymeric material and an improved implant having increased oxidation resistance, as taught by Sun et al.

#### *Proposed Interference*

Claims 12-26, 38-79, 82-89, 93-98 and 101-103 of this application have been copied by the applicant from U. S. Patent No. 6,228,900 or a rewritten to encompass or overlap claims from US Patent No. 6,228,900. These claims are not patentable to the applicant because applicant does not have support within the disclosure as originally filed for the claim language employed, as set forth herein above.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claims be patentable to the applicant subject to a judgment in the interference.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Susan Berman*

Susan W Berman  
Primary Examiner  
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SB

January 3, 2005

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